DOCKET NO.: 01056

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:	:	
DELANSORNE et al.	:	Examiner: B.D. Chisum
SERIAL NO.: 09/787,436	:	Art Unit: 1653
FILED: March 27, 2001	:	

FOR: PHARMACEUTICAL COMPOSITIONS BASED ON ALPHA-CYCLODEXTRIN FOR THE ORAL ADMINISTRATION OF LH-RH ANALOGUES

RESPONSE TO RESTRICTION REQUIREMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Responsive to the requirement for restriction which was made on under 35 U.S.C. §§121 and 372 on September 30, 2002, applicants hereby elect to prosecute the invention of the following peptide, with traverse:

[D-Leu^6-Npg^7-Pro^{9}NHEt]LH-RH,

namely, a peptide ([Npg^7]-leuprorelin) of formula (A) in which Al is pGIu; A2 is His, A3 is Trp; A4 is Ser; A5 is Tyr; A6 is D-Leu; A7 is Npg; A8 is Arg; and Z is NHC_2H_5.

This election is made with traverse for the following reasons:

The present application was filed under 35 U.S.C. §371 as a national phase application of PCT/EP99/07389 and, as such, is subject to the unity requirements set out in PCT Rules 13.1-13.4 and 37 C.F.R. §1.475, as well as the PCT Administrative Instructions

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and Annex B. It is to be further noted that the scope of the claims presently before the U.S. Patent and Trademark Office is identical to that of the claims of the international application.

In the present application, unity of invention has already been reviewed by the International Preliminary Examination Authority during international preliminary examination. No finding of lack of unity was made during the international stage. It is therefore apparent that the International Preliminary Examination Authority has already determined that the criteria of PCT Rule 13 are satisfied in this application.

Furthermore, according to Article 27, paragraph 1, of the PCT, it is not permissible for a national office to require compliance with requirements that are different from or in addition to the implementing rules of the PCT and the Regulations.

In view of the foregoing, it was clearly improper for the Examiner to raise an objection of lack of unity of invention during the US national phase of the present PCT application.

Even assuming, *arguendo*, that it is proper for an objection of lack of unity to be raised in this national stage application, it is Applicants' belief that the Examiner has improperly applied the "unity of invention" criterion of PCT Rule 13.

Under PCT Rule 13, Applicants are entitled to examination of a single inventive concept (unity of invention) as determined by a technical relationship among the groups that involves at least one common or corresponding special technical feature.

Rule 13.1 stipulates that an international application shall relate to an invention or to a group of inventions so linked as to form a single general inventive concept.

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Rule 13.2 explains that a single general inventive concept exists between the inventions of the claims when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features, said "special technical features" meaning those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the present application, the special technical feature that is identical for all the categories of claims is an LH-RH peptide analogue in combination with α-cyclodextrin. This particular arrangement constitutes the special technical feature which is common to the compositions and methods embraced by Claims 21-78, and which defines a contribution which each of these inventions, considered as a whole, makes over the prior art.

The Examiner has determined, however, that the special technical feature of the present invention is somehow known from the Agerholm et al. reference. Applicants respectfully disagree with the Examiner's determination.

Agerholm at al. relates to a powder formulation for intranasal administration containing hGH, didecanoyl-L-α-phosphatidylcholine and α-cyclodextrin (see e.g. paragraph 2 of the experimental section on page 1706, right-hand column).

In sharp contrast, the present claims are directed to pharmaceutical compositions containing an LH-RH peptide analogue in combination with α-cyclodextrin, and to methods of treatment using this combination. There is no disclosure or suggestion of such a combination in Agerholm at al., or in any other art of which Applicants are aware.

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Indeed, Applicants are not claiming α-cyclodextrin *per se* but, rather, the combination of an LH-RH peptide analogue with α-cyclodextrin that represents the special technical feature of the invention.

Since the Examiner provides no credible evidence that this special technical feature does not make a contribution over the prior art, a holding of lack of unity of invention of Claims 21-78 is inconsistent with PCT Rule 13 and 37 C.F.R §1.475. Accordingly, the restriction requirement should be reconsidered and withdrawn.

CONCLUSION

For all of the above reasons, it is urged that claims 21-78 in this application possess unity of invention. Applicants therefore respectfully request that the restriction requirement issued by the Examiner be favorably reconsidered and withdrawn.

Respectfully submitted

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October 29, 2002

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